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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,333	03/06/2002	Paz Einat	EINAT1.1D	1554

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EXAMINER

ASHEN, JON BENJAMIN

ART UNIT PAPER NUMBER

1635

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/091,333

Applicant(s)

EINAT ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 12-16 are drawn to a method for the treatment of a subject for hypoxia or ischemia-related disease comprising administering an antagonist of a polypeptide having a sequence as set forth in SEQ ID NO: 10, or an analogue thereof, classifiable in class 514, subclass 1.
  - II. Claims 17-23 are drawn to an RNA molecule which targets mRNA or DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10, classifiable in class 536, subclass 24.5.
  - III. Claims 24-33 are drawn to a method for the treatment of a subject for hypoxia or ischemia-related disease comprising administering an RNA molecule that targets the mRNA or DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10, classifiable in class 514 subclass 44

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of group I is a method for the treatment of a subject for hypoxia or ischemia-related disease comprising administering an antagonist of a polypeptide having the amino acid sequence of SEQ ID NO: 10. The invention of group II is an RNA molecule which targets mRNA or DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10. In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. The invention of group I will operate by targeting and antagonizing a polypeptide. The invention of group II will operate by targeting a particular nucleotide sequence.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, prior art searches of a method of administering an antagonist of a polypeptide and an RNA molecule which targets mRNA or DNA encoding a polypeptide are not coextensive. Search of each of these inventions would require different key word searches in divergent sequence, patent and non-patent literature databases and would include a search for distinct method steps of group I not required when searching the composition of group II. These divergent searches would then require subsequent in-depth analysis of unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of the inventions of groups I and II together.

3. Inventions of groups I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of group I is outlined above. The invention of group III is a method for the treatment of a subject for hypoxia or ischemia-related disease comprising administering an RNA molecule that targets the mRNA or DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10. In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. The invention of group I operates by targeting and antagonizing a polypeptide. The invention of group III operates by targeting a particular nucleotide sequence.

Furthermore, searching the inventions of groups I and III together would impose a serious search burden. In the instant case, prior art searches of a method of administering an antagonist of a polypeptide and a method of administering an RNA molecule which targets mRNA or DNA encoding a polypeptide are not coextensive. Search of each of these inventions would require different key word searches of the divergent method steps required for administration of different compositions, particularly in regards to an antagonist as claimed, that can be any antagonist of a polypeptide having the amino acid sequence of SEQ ID NO: 10, in, at least, patent and non-patent literature databases. This search would include a search for distinct method steps of group I not required when searching distinct method steps of group III. These divergent searches would then require subsequent in-depth analysis of unrelated prior art literature, placing a serious burden on the Office in terms of both search and

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examination. As such, it would be burdensome to perform search and examination of the inventions of groups I and III together.

4. Inventions of groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The inventions of groups II and III are outlined above. In the instant case, the product that is the invention of group II can be used in a materially different process of using that product, that being as a hybridization probe in an assay of cell or tissue specific gene expression.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, prior art searches of an RNA molecule that targets mRNA or DNA encoding a polypeptide and a method of administering an RNA molecule that targets the mRNA or DNA of a polypeptide are not coextensive. Search of each of these inventions would require different key word searches in divergent sequence, patent and non-patent literature databases and would include a search for distinct method steps of group III not required when searching the composition of group II. These divergent searches would then require subsequent in-depth analysis of unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of the inventions of groups I and III together.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

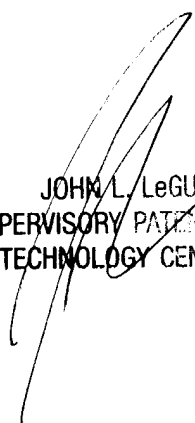
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba



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SUPERVISORY PATENT EXAMINER  
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